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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,009	12/22/1999	JEONG S. LEE	003764.P006	5656
24201	7590	01/04/2006	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			LAM, ANN Y	
		ART UNIT	PAPER NUMBER	1641

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/470,009	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 October 2005.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-15, 17-19, 21-23, 25, 26, 51, 53, 56, 58-60, 64 and 65 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-15, 17-19, 21-23, 25, 26, 51, 53, 56, 58-60, 64 and 65 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-23, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not disclose that the annealed portion of the mandrel is spaced apart from an outer surface of an inner member and an inner surface of an outer member.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15, 17, 18, 51, 53, 56, 58-60, 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Chiu et al., 6,224,535, and further in view of Wantink et al., 6,179,810.

Evard discloses the invention substantially as claimed except for the proximal section of the mandrel being annealed.

More specifically, as to claims 11, 12 and 53, Evard discloses an elongated catheter shaft (10) having a lumen, a mandrel (26) having a solid core comprised of a variable stiffness, non-metal material such as high strength plastic (see column 3, lines 38-42, and column 4, lines 28-30), said mandrel uniformly tapered from a proximal section to a distal section (see column 3, lines 38-42, and Figure 1), and said mandrel adapted to reinforce a catheter (see Figure 1.)

Although Evard teaches that the mandrel may be formed from high strength plastic, Evard does not disclose that the plastic material is PEEK (i.e., polyetheretherketone). Chiu et al. teaches this limitation.

Chiu et al. teaches that a mandrel made from PEEK which has sufficient axial strength to move a sheath (col. 11, lines 53-57.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Evard mandrel from PEEK because Chiu et al. teaches that PEEK is a plastic having sufficient axial strength as would be desirable for the functions of the Evard plastic mandrel.

Also, although Evard teaches that the proximal end of the polymer mandrel (col. 4, line 30) is flattened and secured within the adapter (13) of the catheter by suitable means, such as adhesives (col. 3, lines 49-53), Evard does not list annealing as one of the examples.

Wantink et al. teaches that a polymeric materials may be secured together by suitable means such as heat and fusion bonds and adhesives (col. 3, lines 36-39, and col. 6, lines 6-10.) Heat fusion is the same as annealing, which typically involves heating and cooling. (Heat fusion involves heating and subsequently cooling to room temperature, and thus is the same as annealing.) (Also, annealing, or heating, PEEK, according to Applicant's disclosure and arguments, would stiffen the PEEK material, giving it a higher crystallinity than if it was not annealed, or heated.)

Because both Evard and Wantink et al. teach use of known means to bond polymeric materials and both list adhesives as an example, and Wantink further lists heat fusion as another example, it would have been obvious to one of ordinary skill in the art at the time the invention was made that heat fusion is a functional equivalent to adhesives for bonding a polymeric mandrel to a catheter.

(With respect to independent claims 11 and 51, the annealed proximal end of the mandrel is considered the bonded proximal end, and is distal to a portion of the mandrel that is also annealed.)

As to claims 13 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, i.e., a diameter tapering from the proximal end of the mandrel to the distal end of the mandrel, see Figure 1.

As to claim 14, the catheter comprises an inflatable member (12, 22 and 23) secured to the catheter shaft, wherein said distal section of said mandrel (26) extends to a location along the length of the catheter located in the inflatable member, see Figure 1.

As to claim 15, said distal section of said mandrel (26) extends to a location proximal to the inflatable member (see figure 1.)

As to claims 18, and 51 said mandrel (26) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section (the proximal section is stiffer since the distal section is more tapered.)

As to claims 59 and 65, the mandrel is fixed to the catheter shaft (see column 3, lines 38-39.)

As to claims 58, 60, 64, and 66, an inner tubular member (14) is disposed near the mandrel, wherein the inner tubular member is adapted to receive a guidewire (see column 3, lines 21-26.) Also, as to claim 64, the mandrel is formed of a polymer compatible with a polymer forming the catheter shaft (col. 4, lines 18-30.)

#### *Response to Arguments*

Applicant's arguments filed October 13, 2005 have been fully considered but they are not persuasive.

Applicant argues that Evard in view of Wantink teaches a mandrel with an annealed section which is coextensive with a fusion bonded end section of the mandrel, and consequently Evard in view of Wantink does not disclose a mandrel having both a bonded proximal end section and an annealed section located distal to the bonded proximal end section of the mandrel.

This is not persuasive because Applicant's claims do not preclude the annealed section from being coextensive with a fusion bonded end section. Thus, the heat fused proximal end of

the mandrel is considered the claimed “bonded proximal end section” and the coextensive remainder of the heat fused mandrel is considered the claimed “annealed proximal section”.

As to claim 19, Applicant states that support for the mandrel being spaced apart from the inner surface of the shaft outer member and the outer surface of the shaft inner member can be found in figure 1B. However, the Office does not find that figure 1B provides support for the *annealed* portion of the mandrel being spaced apart from the inner surface of the shaft outer member and the outer surface of the shaft inner member, as recited in claim 19. The written description of the invention also does not provide support for this limitation in claim 19, and thus claim 19 contains new matter as described above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



  
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12/27/05